ATTACHMENT C

ATTACHMENT C: PLAINTIFF'S STATEMENT OF THE CASE

Factual Statement.

On September 27, 2004, the Plaintiff, Jennifer Coker, at the time a 31-year-old woman, had a Bard Recovery filter placed in her inferior vena cava (IVC), the vein that carries blood to the heart as she had experienced recurrent pulmonary embolism while on anticoagulation medicine. An IVC filter is intended as a preventative measure to catch blood clots before they reach the heart or lungs. Defendants designed, manufactured, tested, and sold the Recovery filter. Bard intended the Recovery filter to be a medical device that could be removed (retrieved) from the body.

On October 11, 2004, Ms. Coker complained to her physician of persistent dyspnea on exertion that had been occurring since her discharge from the hospital following placement of the filter.

Later that day, she was taken via EMS to the emergency room for difficulty breathing, severe left-sided pleuritic chest pain, weakness and pre-syncopal symptoms. Pulmonary embolism was excluded. Her INR was therapeutic. Another visit to the emergency room in December 2004 was prompted by chest pain and shortness of breath. Pulmonary embolism was excluded, and she was discharged the next day.

When Ms. Coker was seen by another of her physician's on October 20, 2004, she again reported recurrent chest pain and dyspnea on exertion since her discharge from the hospital following placement of the filter.

In February 2005 Ms. Coker was admitted to Northside Hospital reporting shortness of breath on exertion and chest pressure/heaviness. There was no evidence of pulmonary embolism. A transthoracic echocardiogram noted a significant right to left Patent Foramen Ovale (PFO) (a connection between the right and left sides of the heart) in the bubble study, but a transesophageal echocardiogram did not reveal this.

On March 1, 2005, Ms. Coker was again seen by her pulmonologist and reported that her ongoing dyspnea on exertion was beginning to limit her daily activities. The physician noted that while walking up a flight of stairs, Ms. Coker's oxygen dropped to 88% and her heart rate increased from 87 to 140. The pulmonologist's assessment was of exertional dyspnea and hypoxemia.

In April 2006, Ms. Coker was seen for chest pain in the emergency room once again. Testing was negative for pulmonary embolism. In May, Ms. Coker was seen by a rheumatologist and reported that her shortness of breath had been more pronounced recently.

A retrospective view of imaging performed on May 22, 2006 revealed a linear metallic foreign body within the left ventricle of Ms. Coker's heart, representing one of the legs of the filter. The IVC filter is seen in this image and it is missing a leg

In June 2006, Ms. Coker was again seen in the emergency room to evaluate dyspnea on exertion, left leg swelling and right shoulder pain. Studies were negative for pulmonary embolism, and deep vein thrombosis.

On November 5, 2006, Ms. Coker presented to Tanner Medical Center because of chest pain under her left breast. The chest pain was described as pleuritic. The electrocardiogram and cardiac biomarkers did not suggest coronary ischemia and there was no evidence of pulmonary embolism. She was discharged home but returned the next day as her pain had intensified. This time she was hypotensive and required medications and IV fluids to maintain blood pressure. With this support, her blood pressure normalized. She was treated with narcotics and beta-blockers. Soon afterwards she developed an episode of bradycardia to 40 beats per minute. She was initially not hypoxic and had normal oxygenation on room air but in the course of the night developed hypoxia (78% on room air), which required supplemental oxygen. The cause of hypotension was not immediately clear.

She was monitored in the ICU. Echocardiogram showed evidence of large pleural and mild pericardial effusions but no evidence cardiac compromise by the pericardial fluid. There was no evidence of cardiac tamponade and the right and left ventricular function was normal. The pleural effusion was large and out of proportion to the small pericardial effusion. Diagnostic testing on November 5 did not show any evidence of pulmonary embolism and her INR was 3.4. Because her clinical course worsened, a CT scan was repeated on November 6th. This study now revealed a consolidation of the left lower lobe with an associated pleural effusion.

She was transferred to Northside Hospital. Initial evaluation was notable for relatively stable oxygenation (97% on 2L by nasal cannula) and stable blood pressure. Here her condition worsened, and she developed cough and bloody sputum. Chest X-ray on November 7 showed a large left pleural effusion filling the entire hemithorax and causing collapse of the left lung.

She became hypoxic and needed supplemental oxygen administered by facemask. Because of chest pain, she was started on intravenous narcotics. Her respiratory status worsened, her respiratory rate steadily increased, and she was wheezing. Nursing notes described increased work of breathing. In this setting of physiological stress, she was noted to have episodes of atrial fibrillation. Cardiology evaluation confirmed atrial fibrillation with rapid ventricular response. She had to be intubated for respiratory failure. Chest X-

ray showed a massive left pleural effusion. A small pericardial effusion was also noted on imaging. The assessment was of pleuro/pericarditis.

Due to respiratory failure as a result of a large bloody pleural effusion/pericarditis/myocarditis, Ms. Coker was intubated. After intubation, a chest tube was placed and 1250 ml of bloody pleural fluid was removed consistent with a diagnosis of a hemothorax. Atrial fibrillation resolved after intubation and thoracentesis. Her cardiac enzymes became elevated despite a repeat echocardiogram showing preserved right and left ventricular function and small pericardial effusion.

She developed fevers and myocarditis was considered. Infectious disease's assessment was a Pleuro Pericarditis syndrome. CT scans showed left multiple pulmonary infiltrates. There was no evidence of any interval development of a new pulmonary embolism. She was discharged on November 20^{h}.

Ms. Coker returned for evaluation on November 22, 2006 with positional chest pain 10/10 and electrocardiogram changes characteristic of pericarditis. She was discharged the next day, but returned again on November 24 reporting increasing chest pain not being controlled with pain medicine. The pain was rated a 7/10 and was a pressure-like sensation. While cardiac markers were normal, she had an elevated white count and evidence of metabolic acidosis. Pericardial effusion was present as well as pleural effusions. She became progressively acidotic, developed respiratory failure,

coded, was resuscitated and was intubated again. A chest x-ray raised the concern of pleural hemorrhage. A diagnosis of pleuro-pericarditis was suggested.

On November 29, 2006, Ms. Coker was transferred to Emory Medical Center on a ventilator. A transthoracic echocardiogram once again raised the possibility of a connection (PFO) between the right and left side of the heart at the atrioseptal valve level. Continuing care was provided, and she was extubated on December 10, 2006. Ms. Coker was transferred to a rehabilitation hospital on December 18, 2006 where she remained until December 23, 2006.

Ms. Coker continued under the care of her physicians for the ensuing years. In November 2011, Ms. Coker sought evaluation of back pain and right upper quadrant abdominal pain. A CT scan of the abdomen was performed and compared to an earlier study, in September 2011. The IVC filter was reported in the IVC with the legs extending outside the vessel wall and abutting the right ureter without causing obstruction. An incidental finding was made of a "small linear calcific structure" located in the left ventricle, along the intraventricular septum. It was postulated that this could be a foreign object.

In October 2012 Mrs. Coker was evaluated by a vascular surgeon. His notes indicated that she was concerned about a "broken" IVC filter. She experienced pain in the left calf for two weeks. The pulses in the left foot were diminished and the ankle

brachial index was abnormal in the left leg at 0.8. Exam was not consistent with acute arterial ischemia. A DVT was excluded. Arterial ultrasound showed occlusion of the left popliteal artery. A CT angiogram of the pelvis and lower extremities showed that the IVC filter was in place with legs extending outside the IVC without causing any surrounding bleeding. A metallic fragment was noted in the right peroneal artery. The left popliteal artery was occluded despite chronic anticoagulation.

Dr. Reddy, an interventional radiologist, evaluated Mrs. Coker in November of 2012. He described that in retrospect, the CT scan of the chest obtained in June 2006 demonstrated a small metallic fragment in the left ventricle, which may have been a part of the filter.

She saw Dr. Puskas, a cardiac surgeon, regarding possible operative removal of a filter fragment from the heart. Imaging conducted by him no longer showed a filter fragment in the heart therefore he did not recommend surgery.

Ms. Coker's imaging revealed the following:

1. October 12, 2004 and December 2004. CT scans of the chest. There is no evidence of any foreign body in the heart or chest.

2. February 15, 2005. Chest X-ray. No evidence of foreign body in the lung fields or in the heart.

3. September 14, 2005. CT scan of the chest. This contrast study did not show any metallic object in the heart or chest.

4. May 22, 2006. CT Abdomen. A linear metallic foreign body is in the apex of the left ventricle of Ms. Coker's heart. The IVC filter is seen in this image and it is missing a leg.

5. June 7, 2006. CT Chest PE with contrast. This contrast study reveals a linear metallic foreign body with the left ventricle of Ms. Coker's heart extending from the cardiac inter-ventricular septum into the left ventricular apex.

6. November 5 and 6, 2006. CT Chest with Contrast. This contrast study reveals a linear metallic fragment within the left ventricle of Ms. Coker's heart, likely within the wall of the apex and distal aspect of the interventricular septum.

7. November 7 and 8, 2006. Chest X-ray. A massive left pleural effusion is present.

8. November 7, 2006. Transthoracic echocardiogram. There is a small pericardial effusion without hemodynamic effect. It is is too small per pericardial drainage. There is a massive pleural effusion.

9. November 8, 2006. Abdominal X-ray. Poor tissue penetration limits evaluation. The filter is noted in the upright position. The legs cannot be counted due to poor resolution.

10. November 6 and 8, 2006. CT scans of the chest. A small linear fragment of bright density is present in the apex of the heart.

11. November 19, 2006. CT angiogram of the chest. A small bright signal is seen in the left ventricle suggesting the presence of a linear metallic object.

12. November 27, 2006. CT scan of the chest. The non-contrast images show a small bright, metallic object along the septum of the heart. One of the legs of the filter extends out of the IVC towards the right side of the patient. A large left sided pleural effusion is still present.

13. November 30, 2006. CT scan of the chest. Large left pleural effusion, small pericardial effusion. Metallic object in the left ventricle.

14. November 30, 2006. CT Chest/Abdomen/Pelvis. A linear metallic foreign body is now in the intraventricular septum.

15. December 1, 2006. Echocardiogram. Normal study with no pericardial effusion.

16. December 14, 2006. Chest CT. The linear metallic foreign body in Ms. Coker's body has changed in position within the intraventricular septum.

17. November 30 and December 6, 2006. CT scans of the chest. A metallic object can be seen in the heart.

18. June 6, 2007. CT scan of the chest with contrast. A small bright density is noted in the apex of the heart.

19. April 29, 2011. X-ray of the left knee. There is no evidence of a metallic object along the course of the tibial arteries.

20. September 17, 2011. Contrast CT scan of the chest. A metallic object is seen in the ventricular septum.

21. November 2**,** 2011. CT scan of the abdomen and chest. There are 6 legs and 5 arms. Four arms are attached to the filter and one arm is embedded in the wall of the IVC. A metallic fragment is seen in the left ventricle along the ventricular septum.

22. January 9, 2012. CT scan of the chest. The fragment previously seen is again noted in the heart.

23. November 14, 2012. CT angiogram of the chest, abdomen and lower extremities. The previously seen object is no longer present in the heart. In the IVC, all six legs of the filter are present. There are 4 arms still attached to the filter. A linear metallic fragment is noted within the posterior soft tissues of the right calf partially involving the right peroneal artery and

> extending posterior to the right fibula within the lateral aspect of the deep fibers of the soleus muscle. A linear metallic fragment of the filter is also seen in the right ovarian vein. Many of the legs of the filter have perforated the walls of the inferior vena cava, at least one of them appearing to extend into the right psoas muscle. This imaging also reveals a large osteophyte arising off the right anterolateral aspect of the L3-L4 disc space at the level of the filter.

As shown above, after implantation, Ms. Coker's Recovery filter fractured and sometime between September 2005 and May 2006, a strut embolized to the left ventricle of her heart. Other struts embolized to other parts of Ms. Coker's body as later imaging demonstrated.

The Recovery filter remains implanted in Ms. Coker's inferior vena cava; however, the filter has fractured, and pieces remain in her body as set forth above.

Since the placement of the filter, Ms. Coker has suffered daily.

Plaintiff claims that the Bard Recovery filter is defective and unreasonably dangerous, and that Bard is strictly liability for its design defect and for failure to adequately warn the medical community of the potential dangers arising out of the use of the filter that it knew were reasonably foreseeable. Plaintiff also claims that Bard was negligent in designing, marketing, testing and selling the IVC filter and that Bard also

negligently failed to warn the medical community of the potential dangers arising out of the use of the filter that it knew were reasonably foreseeable and also negligently failed to initiate a recall of their filter.

Plaintiff alleges that Bard is liable for both compensatory and punitive damages.

Given Ms. Coker's complicated medical history spanning years, a succinct factual statement was rendered difficult.

I. Rules, Regulations, Statutes, Ordinances, and Illustrative Case Law.

The Court has considered and ruled upon the Defendants' Motion for Summary Judgment and is thus familiar with most of the legal issues likely to arise in this case. Relevant authorities include, but are not limited to, the following:

A. Strict Liability (General Aspects)

To recover, the person injured by an allegedly defective product must establish that (a) the product was defective, (b) the defect existed at the time the product left the manufacturer's control, and (c) the defect in the product was the proximate cause of the person's injury. *See* O.C.G.A §§ 51-1-11, 51-11.1; *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671 (Ga. 1994); *SK Hand Tool Corp. v. Lowman*, 479 S.E.2d 103 (1996) (en banc); Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 62.610. *See also* Restatement (Second) of Torts §

402A (1963 and 1964).

The manufacturer of a new product that is defective at the time it leaves the hands of the manufacturer and which proximately causes injury to a natural person is strictly liable for the defect and has the burden of loss shifted to it when loss is caused by the defect. O.C.G.A. §51-1-11(b); *Ellis v. Rich's, Inc.*, 212 S.E.2d 373 (Ga. 1975); *Orkin Exterminating Co., Inc. v. Dawn Food Products*, 366 S.E.2d 792 (Ga. App. 1988).

B. Failure to Warn (Negligent and Strict Liability)

To establish a failure to warn claim under Georgia law, "the plaintiff must show the defendant had a duty to warn, the defendant breached that duty and the breach was the proximate cause of the plaintiff's injury." *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999).

"[A] manufacturer has a duty to warn of nonobvious foreseeable dangers from the normal use of its product." *Thornton v. E.I Du Pont de Nemours & Co.*, 22 F.3d 284, 289 (11th Cir. 1994) (citations omitted).

The duty to warn arises "whenever the manufacturer knows or reasonably should know of the danger arising from the use of its product." *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994).

Under Georgia Law, the duty to warn is "breached by (1) failing to adequately

communicate the warning to the ultimate user or (2) failing to provide an adequate warning of the product's potential risks." *Thornton*, 22 F.3d at 289.

In cases involving medical devices, Georgia applies the "learned intermediary" doctrine. Under this doctrine, the manufacturer has no "duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and manufacturer." *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003) (citing *Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272, 1279-80 (11th Cir. 2002)). The manufacturer's warnings to the physician, however, "must be adequate or reasonable under the circumstances of the case." *Id*.

The duty to warn is a continuing one and may arise "months, years, or even decades after the date of the first sale of the product." *Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1218 (11th Cir. 1999).

The general rule in Georgia is that the adequacy of a warning is an issue for the jury. *Thornton*, 22 F.3d at 289.

The "question that must be answered by the fact finder is whether the warning given was sufficient or was inadequate because it did not 'provide a complete disclosure of the existence and extent of the risk involved.'" *Watkins*, 190 F.3d at 1220 (quoting *Thornton*, 22 F.3d at 289*); see Cason v. C. R. Bard, Inc.*, 2015 WL

9913809 at *4-5 (N.D. Ga. Feb. 9, 2015); *Cisson v. C. R. Bard, Inc.*, 2013 WL 5700513 at *7-8 (S.D. W. Va. Oct. 18, 2003).

Defendant's warning can also be in the nature of a recall of a product. Under Georgia law, a manufacturer can be liable for negligently failing to initiate a recall. O.C.G.A. 51-1-11(c); *In re Stand 'n Seal Products Liability Litigation*, 2009 WL 3150417 at *4 (N.D. Ga.), citing *Mack Trucks, Inc., v. Conkle*, 263 Ga. 539, 540-41 (1993) ("[Defendant] is liable on the basis of its 'negligent failure to recall or warn,' . . . a negligence theory of product liability which is recognized under O.C.G.A. § 51-1-11(c)."

See also O.C.G.A. § 51-1-1 (tort defined), 51-1-2 (ordinary diligence), 51-1-6 (breach of legal duty).

C. Design Defect (Negligent and Strict Liability)

Under Georgia law, negligent or defective design is generally a jury question. See *Davis v. Glaze*, 354 S.E.2d 845 (Ga. 1987); *Smokey Mountain Enterprises, Inc. v. Bennett*, 359 S.E.2d 366 (Ga. App. 1987).

Under Georgia law, ordinary negligence means the absence of or the failure to use that degree of care that is used by ordinarily careful persons under the same or similar circumstances. For a plaintiff to recover damages from a defendant in such a case, there must be injury to the plaintiff resulting from the defendant's negligence.

See O.C.G.A.§ 51-1-2; Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 60.010.

Georgia uses a "risk-utility" test for product liability claims. *Banks*, 450 S.E.2d at 674.

"A product may be found defective because of its particular design. Although a manufacturer is not required to ensure that a product design is incapable of producing injury, the manufacturer has a duty to exercise reasonable care in choosing the design for a product." Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 62.640.

To determine whether a product suffers from a design defect, there must be a balancing of the inherit risk of harm in a product design against the utility or benefits of that product design. There must be a determination whether the manufacturer acted reasonably in choosing a particular product design by considering all relevant evidence, including, but not limited to, the following factors:

- the usefulness of the product;
- the severity of the danger posed by the design;
- the likelihood of that danger;
- the avoidability of the danger, considering the user's knowledge of the product, publicity surrounding the danger, the effectiveness of

warnings, and common knowledge or the expectation of danger;

- the user's ability to avoid the danger;
- technology available when the product was manufactured;
- the ability to eliminate danger without impairing the usefulness of the product or making it too expensive;
- the feasibility of spreading any increased cost through product's price or by purchasing insurance;
- the appearance and aesthetic attractiveness of the product;
- the product's utility for multiple uses;
- the convenience and durability of the product;
- alternative designs for the product available to the manufacturer;
- and the manufacturer's compliance with the industry standards and government regulations.

Banks, 450 S.E.2d at 675 n. 6, Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 62.650.

In determining whether a product was defective, the jury may consider evidence of alternative designs that would have made the product safer and could have prevented or minimized the plaintiff's injury. In determining the reasonableness of the manufacturer's choice of product design, the jury should

consider 1) the availability of an alternative design at the time the manufacturer designed this product; 2) the level of safety from an alternative design compared to the actual design; 3) the feasibility of an alternative design, considering the market and technology at the time the product was designed; 4) the economic feasibility of an alternative design; 5) the effect an alternative design would have on the product's appearance and utility for multiple purposes; and 6) any adverse effects on the manufacturer or the product from using an alternative design. Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 62.660.

In determining whether a product was defective, the jury may consider proof of a manufacturer's compliance with federal or state safety standards or regulations and industrywide customs, practices, or design standards. Compliance with such standards or regulations is a factor to consider in deciding whether the product design selected was reasonable considering the feasible choices of which the manufacturer knew or should have known. However, a product may comply with such standards or regulations and still contain a design defect. Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 62.670.

See also O.C.G.A. § 51-1-1 (tort defined), 51-1-2 (ordinary diligence), 51-1-6 (breach of legal duty).

D. Punitive Damages

Under Georgia law, punitive damages may be awarded where "it is shown by clear and convincing evidence that the defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." Ga. Code Ann. § 51-12-5.1(b).

Under the conscious indifference standard, "punitive damages are available where a manufacturer knows that its product is potentially dangerous and chooses to do nothing to make it safer or to warn consumers." *Cisson*, 2013 WL 5700513, at *13 (citations omitted).

Punitive damages are available where a manufacturer knows that its product is dangerous and chooses to do nothing to make it safer or to warn consumers. [*Jones Pretrial Order,* citing Court's Order, dated Nov. 22, 2017 (Dct. 8874), at 19].

Punitive damages are awarded not as compensation to a plaintiff but solely to punish, penalize or deter a defendant. *See* O.C.G.A. § 51-12-5.1(b)(c); Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 66.700, 66.702.

Defendants' alleged compliance with federal regulations does not insulate Defendants from punitive damages. (Doc. 105 at 21).

Further, although under Georgia law, "[o]nly one award of punitive damages

may be recovered in a court in this state from a defendant for any act or omission if the cause of action arises from product liability, regardless of the number of causes of action that may arise from such act or omission," (O.C.G.A. . §51-12-5.1(e)(1), the "one award" limitation does not apply in this case as Defendants have yet to be punished for its acts or omissions regarding the Recover filter. (Doc. 105 at 21-22).

II. Defendants' Acts of Negligence.

A. Bard failed to properly design the Recovery filter because it did not conform to the specifications of its predicate device, the SNF, to which it should have been substantially equivalent.

B. Bard failed to properly design the Recovery filter because it was not designed to withstand its environment of use within the human body.

C. Bard failed to properly design the Recovery filter because it required longer arms, a stronger weld, larger and stronger hooks, increased wire diameter, and an increased leg span.

D. Bard failed to properly design the Recovery filter because it failed to account for the fact that the IVC is a dynamic structure and could expand after implantation of the Recovery filter.

E. Bard failed to properly design the Recovery filter because it was not designed to withstand pressures that could occur within the IVC.

F. Bard failed to properly design the Recovery filter because the design allowed for the filter to tilt within the IVC, leading to failure to prevent blood clots, migration, perforation, fracture, and injury.

G. Bard failed to properly design the Recovery filter because the design allowed for the struts to perforate the IVC, leading to migration, tilt, fracture, and injury.

H. Bard failed to properly design the Recovery filter because the design resulted in an unreasonably high likelihood and rate of fracture, leading to failure to prevent PE, migration, tilt, perforation, migration of fractured struts, and injury.

I. Bard failed to properly design the Recovery filter because struts contained a single attachment point, allowing fractured struts to migrate throughout the body, causing injury.

J. Bard failed to properly design the Recovery filter because the cap had insufficient chamfer, which caused struts to fracture.

K. Bard failed to properly design the Recovery filter because the arm curvature created a stress concentration at the apex of the filter, which caused struts to fracture.

L. Bard failed to properly design the Recovery filter because the arms had weak attachment points, which caused struts to fracture.

M. Bard failed to properly design the Recovery filter because the design would not always engage the filter hooks, and without all hooks engaged, the filter would migrate.

N. Bard failed to properly design the Recovery filter because it designed the filter to resist pressures of 50 mmHg, while pressures within the human body could exceed 50 mmHg.

O. Bard failed to properly test the Recovery filter because it conducted only a limited pilot study before selling it commercially.

P. Bard failed to properly test the Recovery filter because did not sufficiently replicate the environment of use in the human body in its bench tests.

Q. Bard failed to properly test the Recovery filter because it conducted fracture testing that did not move the filter struts far enough, considering what would occur in the human body.

R. Bard failed to properly test the Recovery filter because it conducted fracture testing that did not use sufficient cycles, considering what would occur in the human body.

S. Bard failed to properly test the Recovery filter because it conducted migration testing at 50 mmHg, when it knew that pressures would be higher in the human body.

T. Bard failed to properly test the Recovery filter because it considered but did not test the Recovery filter at 140 mmHg.

U. Bard failed to properly test the Recovery filter because it considered the overall average pressure during migration testing, when individual filters failed to resist migration to the specified pressure.

V. Bard failed to properly test the Recovery filter because it conducted migration resistance testing at temperature that exceeded normal body temperature, and the difference caused a statistically significant difference in test results.

W. Bard failed to properly test the Recovery filter because it did not have an appropriate bench test to evaluate fracture.

X. Bard failed to properly test the Recovery filter because the fracture test it did use was before the sterilization process, which could weaken the filter.

Y. Bard failed to properly test the Recovery filter because it conducted an inadequate finite element analysis.

Z. Bard failed to initiate a recall of the Recovery filter.

AA. Bard failed to adequately warn about risks it knew of regarding the Recovery filter. Bard kept this information from its sales representatives, who were charged with providing risk and benefit information to doctors, and on whom doctors relied (in part) for this information, from doctors, from the FDA, and from the public.

Following is a summary of the information Bard knew but failed to warn about, and that doctors did not know and considered material, including, where relevant, the approximate date of Bard's knowledge:

- The SNF filter had an excellent performance profile compared to the Recovery filter, with very few reports of failures over many years and with thousands of sales. For example, as of September 2005, Bard knew of 1 migration, two fractures, and zero deaths, after over 77,000 unit sales. In contrast, Bard learned of two fractures, two tilts and one migration after just 32 implantations of the Recovery filter, and very short implantation times; Bard predicted at launch that the Recovery filter would fracture approximately 1 in 1,000 filters, or at least 10 times more than the SNF filter, and up to 750 times more often; Bard's prediction for perforation was similarly 10 to 750 times higher than the SNF; by the end of 2004, the Recovery fracture rate was in fact 10 times higher than other filters on the market, and Bard predicted that for every 1,700 filters sold, at least one fracture would migrate to someone's heart or lung; up to 30% of Recovery filters were tilting. Bard calculated that these differences were statistically significant. By July 2004, Bard determined that its Recovery filter required more frequent monitoring, that fractures were "catastrophic," and occurring at a rate that was "unacceptable" according to

Bard's standard operating procedure. By September 2004, Bard had received 24 times as many reports of migration for the Recovery filter compared to the SNF filter after adjusting for different sales figures for each filter, 5 times as many reports of perforation, 12 times as many reports of fracture, and 33 times as many reports of migration plus embolization. In December 2004, Bard concluded that rates of fracture, migration, perforation, and death were approximately 4 times higher in Bard filters than in competitor filters. Nine months later, all of these rates were higher, with 53 times as many fractures. Further analysis in January 2006 again concluded the Recovery fractures were "Unacceptable" and "Must be corrected."

- Bard did not know why the Recovery filter migrated or fractured.
- Bard understood in 2003 that the Recovery filter should be monitored for problems 7, 30, and 60 days after implantation.
- Bard understood in 2003 that the Recovery filter had a flawed design, including a weak weld that caused fractures, and that the design required larger diameter struts.
- The Recovery pilot study was not intended to show safety of the Recovery filter.

- The Recovery filter was fatigue-tested before sterilization, and sterilization could weaken the device.
- In 2003, Bard understood that it needed penetration limiters to minimize penetration but did not include them on the Recovery filter.
- By October 2003, Bard already knew that it had to redesign the filter and was deciding how to do it.
- During bench testing, Bard considered, but rejected a migration resistance threshold of 140 mmHg, and understood that IVC pressure could be as high as 50 mmHg after measuring animal IVC pressures of 69 mmHg. Bard settled on a 30 mmHg maximum pressure with a 25 mmHg "safety margin," resulting in acceptance criterion of 50 mmHg. When tested, the Recovery filter migrated at pressures as low as 7.2 mmHg. The Recovery filter also failed the 50 mmHg threshold at normal body temperature. It passed (only with an average score), only when the temperature was raised above normal human body temperature, which caused a statistically significant increase in migration resistance. Moreover, the SNF filter and competitive filters performed better than the Recovery filter. By May 2004, Bard determined that the appropriate threshold should have been 80 mmHg.

- By February 26, 2004, Bard knew that, contrary to marketing claims, the Recovery filter did not always stay centered.
- By early 2004, Bard determined that the Recovery filter had substantially and statistically significantly more deaths, migrations, and fractures than the SNF and competitor filters.
- By April 2004, the Recovery filter had caused two deaths. Bard stopped selling the filter, but within two weeks determined that it should simply downplay comparisons with other filters, claim that the rates of failure were not significantly different, and start selling the Recovery again while it attempted to fix the problems through a re-design.
- By May 2004, Bard understood that the IVC could expand beyond 28mm (for which the Recovery filter was contraindicated). It determined based on this that bench testing was inadequate, but never updated the test or retested the Recovery filter. Meanwhile, internal guidance about how to handle questions directed employees to claim that the Recovery filter was rigorously tested and met all test specifications and requirements, and failure rates were comparable to those of other filters.

- By June 2004, a medical doctor employee advised that Bard should pull the Recovery filter unless they found that fractures were caused by improper use.
- While attempting to correct the identified design failures in the Recovery filter, Bard continued to market it, which employees recognized was improper. After the G2 filters was launched, Bard told doctors that Recovery problems occurred only in bariatric patients.
- By June 2006, even the purportedly improved G2 filter was fracturing 5 times more than the SNF, perforating 15 times more, and migrating 114 times more; in a clinical trial, there was a 30% failure rate, including 20% of filters tilting, such that the Medical Monitor for the study recommended stopping the study and told his hospital not to buy Bard filters; and a medical doctor advisor concluded based on these data that even the purportedly improved G2 was not substantially equivalent to similar devices; by July 2009, G2 fracture reports were 6 times as high as the SNF, rising to 7 in 2010. All of this related to the G2 made it even more apparent that the Recovery filter, without design changes intended to reduce Recovery filter failures, put patients at high risk of migration, perforation, fracture, and injury.

- Throughout this time—and even today, Bard was misleadingly comparing Recovery and G2 failure rates to a publication it refers to as the "SIR Guidelines," which provides a "Reported Rate" for fractures based on filters marketed in 1993 and 1990. Bard claimed that these literature rates set an acceptable "Thresholds" for the Recovery filter failures, while knowing that voluntary failure reports are underreported and must be multiplied by 20-100 times to properly make comparisons with studies. Thus, the Recovery filter, with, for example, 0.546% of voluntary reports of fractures per unit sales, was likely fracturing in 11-55% of unit sales (and, therefore, at higher rates when adjusting for inventory on shelves, short implantation times, removals, etc.). Bard also improperly reported Recovery filter failures as not serious or life-threatening, even when patients required emergency surgery because of fractures that migrated to other organs. Moreover, Bard understood that doctors believed fracture rates of 1 in 1,000 filters was too high and should be less than 1 in 10,000.

BB. Plaintiff incorporates herein by reference as if fully set forth herein, expert deposition testimony/disclosure reports setting forth the negligent acts of Defendants with regard to the Recovery filter.

CC.

III. Damages.

A. **Compensatory Damages**, including both economic and non-economic damages.

i. Special Damages: Plaintiff seeks to recover for special damages. Special damages are those which actually flow from a tortious act; they must be proved in order to be recovered. *See* O.C.G.A. § 51-12-2(b). In all cases, necessary expenses consequent upon an injury, such as past and future medical expenses, are a legitimate item in the estimation of damages. O.C.G.A. § 51-12-7. The measure of such damages is the reasonable value of such expense as was, or will be, reasonably necessary. Suggested Pattern Jury Instruction, Volume I, Fifth Edition, Council of Superior Court Judges, p. 264. Jennifer Coker's past medical expenses exceed $750,000.00. She continues to incur medical expenses making it difficult to provide an exact amount of past medical expenses until the time of trial. At trial, should the exact figure be less, Plaintiff will obviously ask for the lesser amount.

ii. Non-Economic Damages: Plaintiff is also entitled to recover general damages, which includes past and future pain and suffering. *See*, O.C.G.A. §§ 51-12-2(a), 51-1-6, 51-1-9, 51-1-13, and 51-1-27. Recovery for pain and suffering includes compensation for: (1) interference with normal living; (2) interference with enjoyment of life; (3) loss of capacity to labor and earn money; (4) impairment of

bodily health and vigor; (5) fear of extent of injury; (6) shock of impact; (7) actual pain and suffering; (8) mental anguish; and, (9) the extent to which Plaintiff must limit her activities. *See Food Lion v. Williams*, 219 Ga.App. 352 (1995).

"Pain and suffering is a legal item of damages. The measure is the enlightened conscience of fair and impartial jurors." *See*, Suggested Pattern Jury Instructions, Volume I, Fifth Edition, Council of Superior Court Judges, Section 66.501, pp. 271-273. As part of damages for pain and suffering, Jennifer Coker also seeks to recover for her loss of enjoyment of life and recreation, impairment of body or physical faculties, and disability and disfigurement. The measure of such damages is the compensation for limitations on a person's life created by the injury, as determined by the enlightened conscience of impartial jurors.

Plaintiff's counsel is aware of the Court's requirement for Plaintiff to list in this Pretrial Order the amount of each type of damage she is seeking. General damages by their nature do not lend themselves to a specific valuation especially without having the benefit of seeing how the evidence will be presented at trial. The value of general damages is determined by the enlightened conscience of a jury. Therefore, general damages are unlike special damages, which are more certain and defined. Plaintiff's counsel will not decide what specific amount of general damages they will ask for until

the case is fully presented to the jury. Plaintiff's counsel will decide a specific amount based on how the evidence is presented and received at trial.

In order to comply with the Court's requirement about listing an amount of each type of damage sought, Plaintiff anticipates requesting general damages in a range of $10,000,000.00 to $20,000,000.00 for Plaintiff. Plaintiff objects to any disclosure to the jury of this portion of the Pretrial Order and what ranges Plaintiff anticipates requesting for general damages.

See also, O.C.G.A. § 51-12-3 (direct and consequential damages).

B. **Punitive Damages**

Punitive damages are awarded solely to punish, penalize or deter a defendant. *See* O.C.G.A. § 51-12-5.1(b)(c); Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 66.700, 66.702; *See also,* O.C.G.A. § 51-12-5 (aggravation).

Plaintiff's counsel is aware of the Court's requirement for Plaintiff to list in this Pretrial Order the amount of each type of damage she is seeking. Without having the benefit of seeing how the evidence will be presented and received at trial, Plaintiff's counsel cannot decide what specific amount of punitive damages they will ask for.

In order to comply with the Court's requirement about listing an amount of each type of damage sought, Plaintiff anticipates requesting punitive damages of up to

$100,000,000.00 to punish Defendants. Plaintiff objects to any disclosure to the jury of this portion of the Pretrial Order and what ranges Plaintiff anticipates requesting for punitive damages.